March 31, 2003

Public Information and Records Integrity Branch (PIRIB)
Office of Pesticide Programs
Environmental Protection Agency (7502C)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

RE: Docket ID Number OPP-2002-0049
Reckitt Benckiser Comments on "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach"

Dear Madam/Sir,

Reckitt Benckiser Inc. (Reckitt) is the manufacturer of d-Con® rodenticides. In addition to incorporating brodifacoum as the active ingredient in d-Con®, we also maintain a registration for the technical active ingredient, warfarin. D-Con® rodenticide products are the leading retail brand of rodenticide products sold in the United States. These products provide consumers with a safe, effective and affordable means of controlling mice and rats in their homes. In doing so, consumers can help protect their family and their home from these disease bearing and destructive rodents.

Reckitt is submitting comments regarding EPA's December 19, 2002 document titled "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach". We previously commented on the initial draft of this document which was made available for an "errors only" review in 2001. While we recognize that the Agency has made significant changes to the original document, and has corrected many errors, we still feel that the current version retains many of the original flaws of the original document. These flaws call into question the validity of the presumptions and conclusions presented in the document.

Reckitt is a member of the Rodenticide Registrants Task Force (RRTF). Bergeson & Campbell is submitting extensive comments on behalf of the RRTF. We agree with the positions and statements included in those comments. Therefore, we are limiting our comments to several specific issues.

DISCUSSION

A. EPA's DOCUMENT IS A COMPARATIVE HAZARD ASSESSMENT OF NINE RODENTICIDE ACTIVE INGREDIENTS AND IS NOT A COMPARATIVE RISK ASSESSMENT.

The initial draft of this document was presented as a comparative risk assessment of nine rodenticide active ingredients. The RRTF and registrants of these actives presented substantial comments arguing that the initial version represented a hazard identification and ranking document and not a risk assessment. EPA has attempted to address these comments by renaming the document and describing it as a preliminary assessment of "potential" risks to birds and non-target mammals. However, the manner in which the agency continues to process and present information in the current document still misrepresents this document as a risk assessment. The document continues to rely primarily upon discussions of the acute toxicological hazards of the nine compounds under consideration and the number of wildlife incidents reported to the agency. Additionally, the conclusion section reports the final information in a manner that erroneously portrays risk, not hazard.

EPA defines a true ecological risk assessment as a flexible process for organizing and analyzing data, information, assumptions and uncertainties to evaluate the likelihood of an adverse ecological effect. It "evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors." 63 *Fed. Reg.* 26846 (May 14, 1998).

Risk is designed as the integration of toxicity and exposure. Though not stated, EPA has used a "maximum expected environmental concentration" (MEEC) (See R.A. Brown "Assessing the Environmental Impact of Rodenticides", Buckle & Smith 1994. Rodent Pests and Their Control.) in its assessment of predicted risk. The MEEC is the worst-case scenario and provides a standard measure for between study comparisons. Maximum is an important qualification because it provides a clearer understanding of what is being discussed in the document – the upper limit of hazard without quantification of risk. The qualification also minimizes the chance that EEC is not misinterpreted as an average estimate.

B. INCIDENT DATA CAN ONLY BE USED AS EVIDENCE OF EXPOSURE AND IS NOT DIRECTLY INDICATIVE OF ADVERSE EFFECTS.

The Agency continues to rely heavily on incident data to determine the likelihood (risk) of adverse effects on birds and non-target mammals. There is no discussion in this document to provide a fair, objective presentation of the incident data. Incident data can be used to determine if exposure has occurred, however, the reviewers have neglected to put this information into proper perspective. Exposure does not necessarily equate to a toxic effect. In many of the incidents, death of the bird or mammal was clearly caused by some event other than anticoagulant exposure (e.g.: euthanasia of nuisance animals and death by automobile). When we reviewed the incident data from California, we found that brodifacoum was implicated in the deaths of most of the birds and mammals whenever liver residues of brodifacoum were detected and hemorrhaging were found, irrespective of whether the exposed subject obviously died from some other cause, such as euthanasia or an automobile trauma. The investigators in both California and New York rely heavily on the presence of hemorrhaging to support their implications of brodifacoum's role in causing illness or death. The presence of hemorrhaging cannot automatically be assumed to be the result of anticoagulant poisoning. Hemorrhages can also be a consequence of disease or injury. We feel the continued presentation of information in this manner displays a particular desire by the reviewers to elicit a specific result.

C. EPA'S COMPARATIVE DOCUMENT INAPPROPRIATELY APPLIES INFORMATION EQUALLY TO ALL INGREDIENTS IN THE ASSESSMENT.

The comparative document has done an injustice to the active ingredients assessed by implying that the results from all studies may be applied evenly and more broadly than each study's intent. We feel this is a critical error in the analysis methodology. By methodology, the secondary toxicity assessment is a meta-analysis: a study that combines the results of a number of relatively small studies to obtain a larger experiment size and, hopefully, more precise and accurate analysis of an issue. For example, the number of exposed and surviving animals in 11 laboratory studies involving 8 species are totaled and then used to arrive at an assessment of 42% mortality of birds exposed to prey deliberately poisoned with brodifacoum. This 42% mortality value is deemed to be the average mortality estimate for brodifacoum, a value then compared to that obtained for the other rodenticides. Based on this, EPA concludes that brodifacoum has the highest secondary toxicity to birds of all the alternative rodenticides.

There are four issues with this.

1. For meta-analysis to be valid, the studies between rodenticides should be comparable or, if possible, made comparable via the judicious exclusion of studies that, for example, do not have a common methodology across rodenticides. The report points out that "Although exposure scenarios, test species, and the number of test animals vary among the studies, collectively they provide sufficient information to characterize secondary toxicity from short-term exposure" (***page 23***). This overstates the implied value of any comparisons between rodenticides. No attempt was made to make the data on actives directly comparable to each other.

2. The 'mean' mortality (eg: 42% for brodifacoum) is estimated by summing the frequencies of the number of dead and the number of surviving animals across all studies. This is a reasonable approach only if the studies within each rodenticide were of relatively equal sample sizes, methodologies etc. This is clearly not the case. Injudicious pooling can mean that studies with larger sample sizes will contribute more to the estimate of the mean that those with smaller samples sizes. The mean estimated is thus a 'weighted' mean with weights provided by the study sample sizes. The implicit assumption is that studies with larger samples are more important than those with smaller sample sizes and so should be weighted to provide more information in the estimation of the mean. This might not be the case, the quality of the different studies must also be considered. A poor study with a large sample size only produces a large amount of poor data!

   Using weighted means for comparisons between rodenticides is even more problematic for similar reasons.

   In the absence of insufficient knowledge of study quality, an 'unweighted mean' would give a more unbiased estimate of the mean. An unweighted mean is calculated by determining the mortality in each study then using these values to estimate the mean mortality of all studies. Each study now makes an equal contribution to the overall mean. The unweighted mean mortality in the bromadiolone exposed birds becomes 20.7% compared to the weighted mean of 8.0%; for mammals the unweighted mean is 28.2% compared to the weighted mean of 23%.

3. The laboratory studies focus very strongly on the risks of agricultural uses of the rodenticides. The predators and scavengers used in the studies are exposed to very high levels of poisoned prey (e.g. two or more fully-dosed rodents per day for a number of days). How relevant are these data to urban usage of the rodenticides in the U.S.? Urban, homeowners are usually dealing with only 1-2 rodents in their home in any one year; and then, at only certain times of the year. The use of rodenticides in

the poorer urban neighborhoods where the pest pressures may be relatively high ought to have few secondary poisoning concerns to wildlife.

To some extent the concern expressed here are considered on ***Page 99***. However, a discussion of the problems with the secondary hazard data needs to be made at the time the data is presented so that the reader is aware from, up front, of the data limitations.

4. The laboratory studies are worse-case scenarios that may have no basis on reality, except in rare plague events in agricultural settings. Many of the studies aimed to specifically achieve a lethal endpoint. Some studies (e.g. ICI 1979a, Mendenhall & Pank 1980) even continued to expose animals to dosed prey for ever longer periods even though the data clearly suggested that further exposure was highly likely to be lethal. The use of all these data, with no appropriate vetting, perhaps over-exaggerates mortality rates.

D. EPA'S COMPARATIVE DOCUMENT MAKES NO ATTEMPT TO CONDUCT A RISK/BENEFIT ASSESSMENT.

Rodents, such as mice and rats are considered to be public health pests by EPA (See EPA PR-Notice 2002-1). Rodents are known to spread a number of diseases such as plague, leptospirosis and salmonellosis and hantavirus pulmonary syndrome, a highly fatal human illness. Researchers at Johns Hopkins University have determined that mouse dander and urine may be major contributors to asthma in children.

FIFRA, under Section 2 (bb), mandates that "in weighing any regulatory action concerning a public health pesticide under this Act, the Administrator shall weigh any risks of the pesticide against the health risks such as diseases transmitted by the vector to be controlled by the pesticide." EPA must consider the risks AND benefits of public health pesticides. There is no discussion or consideration of the public health benefits of rodenticides in the comparative assessment document. These products are essential to help people control the rodent populations in their homes in order to prevent disease and property damage. While the Agency has indicated that it will conduct this risk/benefit analysis later in the evaluation process, we feel EPA has done a disservice to the public by releasing a document that does not present a fair and balanced discussion of the benefits versus the hazards (risks) of rodenticides. Reading this document without the advantage of an unbiased benefits discussion could lead some readers to deduce that the risks outweigh any benefits that occur from having consumers control rodent populations themselves in their homes.

CONCLUSION

Reckitt Benckiser feels that EPA has not sufficiently completed an appropriate assessment of the primary or secondary risks to birds and mammals in order to move to the next phase in the assessment process. The Agency has ranked the active ingredients according to hazard, but has not demonstrated a risk from any one chemical that would require specific mitigation measures. EPA must consider the public health benefits of these products and continue to ensure that consumers have safe, effective and affordable products to use in their homes in order to mitigate the health and safety risks from rodents.

Thank you for your consideration of these comments.

Sincerely,

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